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Chlormequat Chloride (PC 18101)

Pre-submission Meeting

Taminco, a subsidiary of Eastman Chemical Company – EPA

July 14, 2016

Agenda

Preregistration Meeting between EPA and Taminco, a subsidiary of Eastman Chemical Company

Chlormequat Chloride (PC 18101)

July 14, 2016
11:00 am – 12:00 pm

- Introductions

  Attendees:

Taminco/Eastman:	John Hott (regulatory affairs)
	Jessica McLaughlin (regulatory affairs)
	John Kelly (regional crop protection manager)
VJP Consulting:	Vince Piccirillo (regulatory agent)
Via Phone:	Lieven Uytterhaegen (regulatory affairs)
	Floortje Garreyn (regulatory affairs)
	Khalid El Ouadi (regulatory affairs)
	David Kossor (toxicologist)

- Taminco's Regulatory Approach
- Background of Chlormequat Chloride
- EPA Data Requirements to support Section 3 TGAI
- EPA Data Requirements to support Section 3 End-Use Product
- Discussion

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Taminco's Regulatory Approach

Phase 1

- Taminco will submit an import tolerance petition for chlormequat chloride on wheat, barley, and oats under PRIA R280 in July 2016

Phase 2

- Taminco will seek a Section 3 registration for a TGAI of chlormequat chloride that will be used to formulate our end-use product
- Taminco will seek a Section 3 registration for End-Use Product (containing 54.87% chlormequat chloride by weight) for use as a growth regulator on wheat, barley, and oats

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Current Registered Uses of Chlormequat Chloride

- Greenhouse, nurseries, shade houses and outdoor containerized ornamentals

Taminco's Proposed Use of Chlormequat Chloride

- First food use on wheat, barley, and oats

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Chlormequat Chloride

- Chlormequat chloride is a plant growth regulator (PGR) that inhibits the action of gibberellic acid, resulting in shortening and strengthening of stems in plants and reduced branching in foliage in certain species of shrubs and trees.

- EPA refers to chlormequat chloride as a low-risk pesticide in the RED.

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End-Use Product - Lodging Control

Wheat

- Treated
- No lodging at Harvest
- Above average yield

- Untreated
- 60% Lodging at harvest
- Massive yield impact

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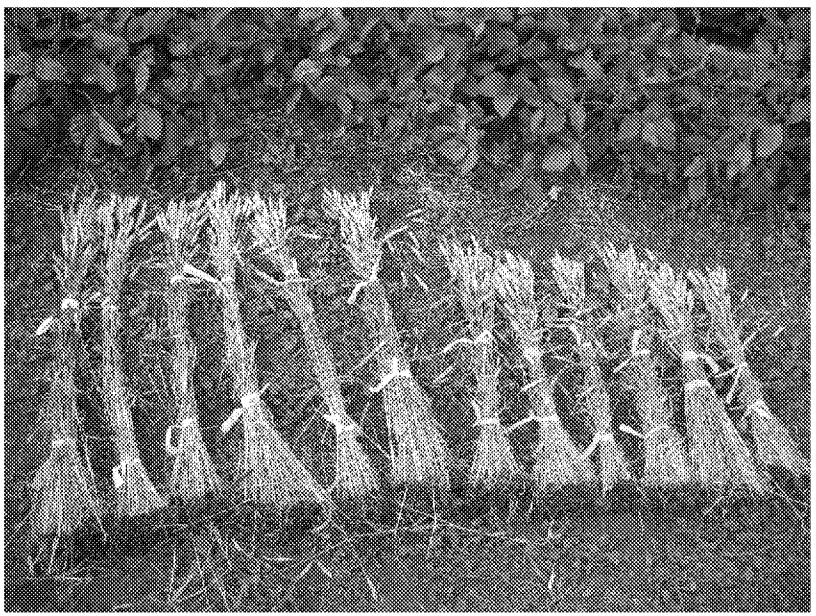
End-Use Product - Reduced Plant Height

Wheat



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Data Requirements to Support Section 3 TGAI Registration

Product Chemistry Requirements

- Technical Chlormequat Chloride at 66% is registered by Fine AgroChemical
- Taminco owns all data submitted to support Fine AgroChemical TGAI registration
- We will cite our own data

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Data Requirements to Support Section 3 TGAI Registration

Toxicology

- Required acute toxicity studies, repeated dose oral and dermal studies, developmental toxicity studies, reproductive toxicity studies, genetic toxicity studies, chronic toxicity and oncogenicity studies and metabolism/pharmacokinetics studies owned by Taminco were previously submitted to USEPA in support of a technical registration and will be cited for this Section 3 registration
- Acute Neurotoxicity (ANT) Study
  - Will be initiated to support Section 3 registration
- Subchronic Neurotoxicity Study
  - Conditionally required based on results of ANT study
- Immunotoxicity
  - Based on existing data, a waiver request will be submitted

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Data Requirements to Support Section 3 TGAI Registration

Applicator Exposure

- Will cite data from Ag Handler Exposure Task Force

Post-Applicator Exposure

- Will cite data from Ag Reentry Task Force

Taminco US LLC is a member of both AHETF & ARTF

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Data Requirements to Support Section 3 TGAI Registration

Environmental Fate

- Aerobic Soil Metabolism Study
  - MRID 46715225 classified as supplemental because all transformation products > 10% may not have been identified. Taminco conducted a new study in 2006. No metabolites exceeding 2.6 % AR were found. This report will be submitted to EPA.
  - Rapid degradation of chlormequat chloride in soil: Half lives range from 30 to 40 days in MIRD 46715225 and10 to 37 days in the new Taminco study.

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Data Requirements to Support Section 3 TGAI Registration

Environmental Fate – Cont.

- Aerobic Aquatic Metabolism Study
  - MRID 46715227 was classified as supplemental. Non extractable residues were uncharacterized. A new study or limited study may be initiated based on review of the study on file.
- Anaerobic Soil Metabolism
  - In view of the spring application timing of the end-use product on cereals, no anaerobic conditions would be expected. Furthermore CCC has a relative short half-life. Therefore we believe it is justified to waive this study.
- Anaerobic Aquatic Metabolism
  - In view of the fast degradation of CCC in water-sediment systems, we believe this study should not be required.

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Data Requirements to Support Section 3 TGAI Registration

Environmental Fate – Cont.

- Terrestrial Field Dissipation Study
  - A waiver request will be submitted to EPA
    - Chlormequat Chloride will be applied to dense fields of non-row crops - Foliar Dissipation will predominate
    - Low application rates
    - Short half-life of parent in soil with low levels of metabolites (10- 43 days).

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Data Requirements to Support Section 3 TGAI Registration

Terrestrial and Aquatic Non-Target Organisms

- Freshwater Invertebrate LC50 (TGAI)
  - Will cite 138719 as this has been deemed acceptable for Risk Assessment
- Estuarine and Marine Toxicity – Fish, Mollusk, Shrimp (TGAI)
  - As wheat, barley and oats are not grown in areas where marine and estuarine environments occur, a waiver will be requested for these studies.

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Data Requirements to Support Section 3 TGAI Registration

Terrestrial and Aquatic Non-Target Organisms – Cont.

- Freshwater Fish LC50 – Cold Water Species (TGAI)
  - Will cite 46715217 as this has been deemed acceptable for Risk Assessment
- Aquatic Invertebrates Life Cycle - Freshwater
  - Will cite 46715216 along with 46715215 as this has been deemed acceptable for Risk Assessment
- Fish Early Life Stage - Freshwater
  - Will cite 47769401 and 47769402 to fulfil this data requirement

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Data Requirements to Support Section 3 TGAI Registration

Terrestrial and Aquatic Non-Target Organisms – Cont.

- Avian Acute Oral – Passerine
  - Will be initiated to support Section 3 registration
- Avian Acute Oral – Quail or Duck
  - Will cite 46715211 as this has been deemed acceptable for Risk Assessment
- Avian Dietary Toxicity – Quail
  - Will cite 46715212 as this has been deemed acceptable for Risk Assessment

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Data Requirements to Support Section 3 TGAI Registration

Terrestrial and Aquatic Non-Target Organisms – Cont.

- Avian Dietary Toxicity – Duck
  - We will cite 46715213 as this has been deemed acceptable for Risk Assessment
- Avian Reproduction – Quail
  - No quail reproduction study was required for re-registration, we believe this study should not be required
- Avian Reproduction – Duck
  - Study requirement seems to have been dropped from previous registrations for Chlormequat Chloride

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Data Requirements to Support Section 3 TGAI Registration

Non-Target Insects

- Honey Bee Acute Contact LD50
  - MRID 46715224 was acceptable during 2007 RED

Non-Target Plants

- Seedling Emergence – Tier 1
  - Has been initiated to support Section 3 registration
- Vegetative Vigor – Tier 1
  - Has been initiated to support Section 3 registration

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Residue Assessments – Summary

Wheat:

- 6 trials in Canada (2015), including 1 trial analyzing aspirated grain fractions (AGF)
- 17 trials in USA, includes 2 decline and 2 processing trials
- Processed fractions
  - Pre-processing RAC grain
  - Bran
  - Flour
  - Middlings
  - Shorts
  - Germ

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Residue Assessments – Summary

Barley:

- 10 trials in USA, including 1 decline and 1 processing trial
- 10 trials in Canada, including 2 decline and 1 processing trial
- Processed fractions:
  - Pre-processing RAC grain
  - Pearled barley
  - Bran
  - Flour

Oats:

- 18 trials in USA, including 2 decline and 2 processing trials
- Processed fractions:
  - Pre-processing RAC grain
  - Rolled oats (groats)
  - Flour

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End-Use Product

Unique product contains:

- Chlormequat Chloride (54.87%)
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Ex. 4 CBI

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Data Requirements to Support Section 3 End-Use Product Registration

Product Chemistry Requirements

- We will submit Group A and Group B Product Chemistry to support our End-Use Product

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Data Requirements to Support Section 3 End-Use Product Registration

Toxicology

- A full six pack has been conducted on the end-use product
  - Acute Oral – LD50 is between 300 mg/kg (Tox II) and 2,000 mg/kg (Tox III)
  - Acute Dermal – Tox III
  - Acute Inhalation – Tox IV
  - Primary Eye Irritation – with 2 animals tested – Tox III
  - Primary Dermal Irritation – with 2 animals tested – Tox IV
  - Dermal Sensitization – Not a Sensitizer

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Thank you!

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